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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James B.D. PALMER ✓

Serial No. 07/753,907 ✓

Filed: September 3, 1991 ✓

For: MEDICAMENTS ✓

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Group Art Unit: 125 ✓

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INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Applicant at this time wishes to direct the attention of the Examiner to the following information which may be material to the prosecution of the above identified application. The publications are listed on attached Form PTO-1449 and a copy of each is submitted herewith for the convenience of the Examiner.

In essence, the most relevant prior art of which applicant is aware is described in the specification in the first complete paragraph on page 2, and comprises the combination of salbutamol and beclomethasone dipropionate, which is marketed under the trademark VENTIDE® by a subsidiary of the assignee of the present application.

Submitted herewith are copies of the entries for VENTIDE® INHALER and VENTIDE® ROTOCAPS from the Association of the British Pharmaceutical Industry (ABPI) Data Sheet Compendium 1989-90 (published April 1989). Also submitted is a copy of PCT specification WO87/05213, which illustrates in Example 4 a specific form of inhalation composition containing this combination of ingredients.

Applicant notes that the ABPI data sheets confirm the need for administration of VENTIDE® up to four times daily, *i.e.* typically at 4-hour intervals in the context of a normal waking day. As is indicated in the present specification, this can cause problems in ensuring patient compliance, and is less than satisfactory as regards treatment of nocturnal

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asthma, with consequent possible impaired sleep for asthmatics troubled by nocturnal cough, breathlessness and wheeze.

The fundamental advantage of the compositions of the present invention is their prolonged duration of bronchodilator activity, permitting administration on a twice-daily basis. This greatly assists in ensuring patient compliance and renders the compositions of substantial value in the treatment of nocturnal asthma.

Respectfully submitted,



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